

### **3. Remarks/Arguments**

Applicants respectfully note that the latest Office Action stated that claims 1-8, 17-26 and 29-36 are pending. This may not be accurate: in the CPA and accompanying amendment filed 3/4/03 (Paper No. 27), Applicants cancelled claims 1-8 and 29-30. Therefore, it appears claims 17-26 and 31-36, are pending in the application with claims 19 and 20 being in independent format. If we are incorrect, please notify us so that we may resolve this issue.

### **Formal Drawings**

The Examiner has requested formal drawings, but this application was not filed with drawings. This mistake has been perpetuated from a previous Final Office Action (Paper No. 21). As you may recall, the Examiner sent a draftsman's review form from an unrelated application, and after discussing the matter over the phone, it was returned to the Examiner. Applicants request that the requirement for formal drawings be withdrawn.

### **35 U.S.C. §112**

Claims 1-8, 17-26 and 29-36 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement. (As noted above, it appears that claims 1-8, 29 and 30 have been canceled and therefore this response will address the rejection of claims 17-26 and 31-36 under 35 U.S.C. §112, first paragraph.) Applicants have amended claims 19 and 20 to more precisely define the invention. Applicants kindly request reconsideration of the amended claims.

The Examiner states at page 4 of the Office Action:

The instant invention encompasses any "flt3 ligand polypeptide" of any "mammal" or "at least 90% identical to the amino acids 28-160 of SEQ ID NO:6" as well as "fragments thereof;" yet the instant specification does not provide sufficient guidance and direction as to the structural features of said scope of "flt3 ligand polypeptides" and "fragments thereof" and the correlation between the chemical structure and the desired molecules or specificities. The reliance on the disclosed limited examples set forth in the specification does not support the enablement for any "flt3 ligand polypeptide" or "fragment thereof," encompassed by the claimed invention.

In response, Applicants have amended the claims 19 and 20 to remove the term "flt3 ligand polypeptide" and have limited the claims to a specific human sequence (SEQ ID

NO:6). Therefore, claims 19 and 20 cannot be interpreted as reading on "any flt3 ligand polypeptide from any mammal," etc.

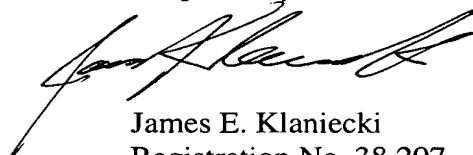
Applicants believe that the claims as amended are fully enabled by the specification. Applicants disclose the cDNA and polypeptide sequences for human (SEQ ID NO:6) and murine (SEQ ID NO:2) Flt3 ligand, as well as fragments that are able to bind a flt3 receptor. Applicants' specification teaches procedures for making biologically active variants at page 8, line 5, *et seq.*, as well as in Examples 3 and 4 (beginning at page 29). The specification also teaches isolating additional variants by techniques such as cross-species hybridization techniques (see Example 4 at page 34). Applicants note that additional procedures for making variants that have at least 90% identity and retain biological activity are conventional in the art.

The application teaches several assays that may be used to identify flt3-ligand polypeptides that are a fragment of SEQ ID NO:6 or are at least 90% identical to SEQ ID NO:6 by screening for binding to flt3. (See page 16, line 26 to page 19, line 2 for various flt3 binding assays, as well as Examples 10 and 11 for biological function assays). Assays of this sort were routinely performed at the time the application was filed.

Given that the state of the art and the level of ordinary skill are quite high, and that the nature of the invention is such that this type of experimentation is routine, Applicants firmly believe that one of skill in the art would be able to make and use the presently claimed invention using Applicants' original disclosure without undue experimentation. As such, Applicants respectfully request the rejection under 35 U.S.C. §112 be properly withdrawn.

Reconsideration and allowance of the pending claims is kindly requested.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Date: Nov. 3, 2003

Signed:   
Nanci M. Kertson

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Resp. to OA dated June 2, 2003